

Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc. and Norton (Waterford) Ltd. (collectively, “Teva”) and Defendants Cipla Ltd., (“Cipla”) and Aurobindo Pharma Ltd.,

Aurobindo Pharma USA, Inc., and Aurolife Pharma, LLC (collectively “Aurobindo”)¹ hereby submit their Joint Claim Construction and Prehearing Statement (“JCCS”) filed in accordance with Local Patent Rule 4.3.

I. Background

This Hatch-Waxman case arises out of Defendants’ filing of Abbreviated New Drug Application (“ANDA”) Nos. 211434 (Cipla) and 214418 (Aurobindo), seeking approval to market generic versions of Teva’s QVAR®, a beclomethasone-dipropionate inhaler that is indicated for the treatment of asthma. Teva asserts that the making, using, selling, offering for sale, or importation of the products that are the subject of these ANDAs would infringe five of Teva’s patents: U.S. Patent Nos. 9,463,289 (“the ’289 patent”), 9,808,587 (“the ’587 patent”), 10,086,156 (“the ’156 patent”), 10,561,808 (“the ’808 patent”), and 10,695,512 (“the ’512 patent”) (collectively, the “Asserted Patents”) under 35 U.S.C. § 271. Defendants allege that the asserted claims are invalid and/or not infringed.

Pursuant to Local Patent Rule 4.1, on April 30, 2021, the parties exchanged proposed terms for construction for the Asserted Patents. Pursuant to Local Patent Rules 4.2(a)-(b), on May 21, 2021, the parties exchanged preliminary claim constructions and identified intrinsic as well as extrinsic evidence in support of their preliminary claim constructions for the Asserted Patents. In accordance with Local Patent Rule 4.2(c), the parties exchanged identifications of all intrinsic and extrinsic evidence that each party intends to rely upon to oppose any other party’s proposed construction on June 4, 2021. Throughout these exchanges, and continuing throughout the filing of this JCCS, the parties have met and conferred in good faith to narrow the number of disputed

¹ Throughout this pleading, “Defendants” refers collectively to Cipla and Aurobindo.

terms. As reflected below, the parties have reached agreement with respect to the construction of 20 terms and dispute 19 additional terms.²

II. Construction of Patent Terms.

A. Agreed Constructions

The parties agree to the construction of the terms set forth below for purposes of this action.

Teva contends that each term identified by Defendants for construction in the Asserted Patents should be interpreted according to its plain and ordinary meaning and does not require construction. Teva agrees to the entry of these constructions because they resolve the specific concerns raised by Defendants over the course of the parties’ oral negotiations in the context of this case. Teva does not suggest or otherwise concede that these constructions would be appropriate outside the context of this litigation.

Defendants agree that the terms should be interpreted according to their plain and ordinary meaning when such meaning exists, however the parties disagree as to that plain meaning as reflected by the parties’ disputes. The parties’ arrived at agreed upon constructions after hours of negotiations, clearly indicating that a dispute is present as to the plain meaning of the disputed terms. Defendants agreed to these constructions as a compromise in an effort to reduce the number of disputes arising from the parties’ initial differing constructions of the terms.

No.	Term	Agreed-upon Construction
1	“canister housing” '289 patent, claim 1 '587 patent, claims 1, 12, and 13	“the portion of the inhaler body that is arranged to retain a medicament canister”
2	“inside surface”	“an interior surface”

² Although 19 terms may still be in dispute, several of the terms relate to one another and Defendants expect that these terms will be addressed together. As such, Defendants consider it more accurate to say that there are 14 claim construction groupings left in dispute. Plaintiffs believe that, however characterized, 19 separate terms or 14 term “groupings” reflects an unnecessarily large imposition on the Court’s time and resources.

	'289 patent, claim 4 '587 patent, claims 4 and 17	
3	"body" '156 patent, claim 1	"the body of the inhaler"
4	"associated with" '156 patent, claim 1	"related to"
5	"canister support formation" '289 Patent, claims 1, 4 '587 Patent, claims 1, 4, 11-13, 15	"a formation arranged to reduce canister rocking"
6	"actuator" '156 Patent, claims 1, 2, 12 '512 Patent, claim 1, 5	"A structure within the dose counter that can be moved by the canister, is moveable relative to other components of the dose counter, and effectuates movement of at least one additional dose counter component."
7	"actuator pawl arranged to engage with a first tooth of the ratchet wheel" '156 Patent, claim 1	"a pawl that is a part of the actuator of the dose counter that is arranged to engage with a tooth of the ratchet wheel."
8	"wall surfaces separating the canister receiving portion and the counter chamber" '156 Patent, claim 1	"wall surfaces of the inhaler body which are substantially perpendicular to the direction of canister movement and which divide the canister-receiving portion and counter chamber"
9	"pins" '512 Patent, claim 1	"shafts that extend through or into respective apertures"
10	"chassis" '512 Patent, claim 1	"frame of the dose counter"
11	"regulator" '808 Patent, claims 1, 27	"a structure of the dose counter that modulates motion of the counter display"
12	"regulate motion of the counter display" '808 Patent, claim 1	"modulate motion of the counter display"
13	"a pin or aperture heat staked to a respective aperture or pin" '512 Patent, claim 1	"a pin or aperture that is secured to a respective pin or aperture using a heat probe to compress and reform or deform the pin"
14	"fixed to the body"	"connected to the body"

	'512 Patent, claim 3	
15	"ratchet wheel" '156 Patent, claims 1, 9, 12	"a wheel having a plurality of circumferentially spaced teeth arranged to engage with a pawl"
16	"first direction" '808 Patent: 1	"single direction at a time"
17	"main surface of the inner wall" '289 Patent, claim 1 '587 Patent, claim 1, 12, 13	"inside surface of the vertical cylindrical portion of the inhaler body, where vertical means substantially parallel to the primary direction of the movement of the medicament canister when it is pressed downward by the user to expel medicament"
18	"inner wall through which a portion of the actuation member extends" '289 Patent, claim 3 '587 Patent, claims 3, 13	"an internal wall of the inhaler body that is horizontal, through which a portion of the actuation member extends, where horizontal means substantially perpendicular to the primary direction of the movement of the medicament canister when it is pressed downward by the user to expel medicament"
19	"inner wall" 289 Patent, claims 1, 4 '587 Patent, claims 1, 4, 12, 13, 15, 21, 22	"an internal wall of the inhaler body, which includes a main surface of the inner wall and the inner wall through which a portion of the actuation member extends, but excludes the bottom surface, or floor, of the inhaler body"
20	"protects against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler" '587 patent, claim 1	"guards against unwanted actuation by reducing rocking of the medicament canister relative to the main body of the inhaler that would otherwise be of a magnitude sufficient to move the dose counter's actuator enough to cause unwanted incrementing (or decrementing) of the dose counter"

B. Disputed Constructions

Pursuant to Local Patent Rule 4.3(b), attached hereto as Exhibit A is a claim chart identifying the claim terms in dispute, the parties' proposed constructions, and the evidence (both intrinsic and extrinsic) that each party intends to rely on in support of its proposed construction or to oppose the other party's proposed construction. Included in the below table is a summary of the disputed claim terms and their corresponding asserted claim numbers.

Again, Teva contends that each term identified by Defendants for construction in the Asserted Patents should be interpreted according to its plain and ordinary meaning and does not require construction. Teva has proposed the following constructions in order to join issue with Defendants' positions. Teva does not suggest or otherwise concede that these constructions would be appropriate outside the context of the specific disputes raised by Defendants.

Again, Defendants disagree that Teva's constructions are consistent with the plain and ordinary meaning in view of the claims and specification. Moreover, given the parties' disputes as to the meaning of these terms, Teva's proposal that disputed terms need not be construed would not resolve disputes as to the meaning of the terms. *See O2 Micro International, Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1361-62 (Fed. Cir. 2008).

Many of the disputed terms below also appear in the parties' proposed constructions. To the extent a disputed term appears in a party's proposed construction, that term should be given either that party's proposed construction, or if the Court does not adopt that party's proposed construction of the term, the construction ultimately adopted by the Court.

No.	<u>Term</u>	<u>Plaintiffs' Construction</u>	<u>Defendants' Construction</u>
1	<p>"actuation member"</p> <p>'289 Patent, claims 1, 3</p> <p>'587 Patent, claims 1, 3, 11, 12, 13</p> <p>'156 patent, claims 12</p>	<p>Plain and ordinary meaning in view of the claims, specification, and prosecution history.</p> <p>"a component of the dose counter's actuator that transmits motion from the canister to the actuator"</p>	<p>"pin arranged to engage with a medicament canister and effect movement causing the dose counter to record a count"</p>
2	<p>"[lying or lie] in a common plane coincident with the longitudinal axis X"</p>	<p>Plain and ordinary meaning in view of the claims, specification, and prosecution history.</p> <p>Features lie on a common plane coincident with the</p>	<p>"aligned in a single plane such that a straight line can be drawn through the center of the central outlet port, a canister support formation located directly adjacent to the actuation</p>

	'289 Patent, claim 1 '587 Patent, claims 1, 12, 21, 22	longitudinal axis X if it is possible to draw a straight line connecting those features that passes through the center of the stem block.	member, and the actuation member”
3	“positioned at opposite ends of the inside surface of the main body to face each other” '289 Patent, claim 7 '587 Patent, claims 7, 18	Plain and ordinary meaning in view of the claims, specification, and prosecution history. “located on opposite sides from one another on the inside surface of the main body, and extending outwardly from the inner wall towards each other”	“positioned directly across from one another such that a straight line can be drawn from one support rail through the center of the longitudinal axis X to the facing support rail”
4	“step[(s)] formed thereon” '289 Patent, claims 5, 8 '587 Patent, claims: 5, 8, 16, 19	Plain and ordinary meaning in view of the claims, specification, and prosecution history. “a location of changing width dimension thereon”	“A stepwise increase in the extent to which the support rail extends inwardly”
5	“first reset position” '156 Patent, claim 1	Plain and ordinary meaning in view of the claims, specification, and prosecution history. “a position of the actuator in which the actuator pawl is brought into engagement with the first tooth of the ratchet wheel and which is before the canister fire configuration”	“configuration in which the actuator pawl is above the datum plane, but closer to the datum plane than in the start configuration, and is just engaged with one of a tooth of the ratchet wheel”
6	“canister fire sequence” '156 Patent, claim 1	Plain and ordinary meaning in view of the claims, specification, and prosecution history. “a sequence of configurations and positions that occur before, while, and after the medicament canister fires medicament”	“process of ejecting medicament from an inhaler where the actuator pawl follows a particular sequence of movement from the start configuration to the reset configuration, to the [fire configuration as, to the count configuration, before returning to the start configuration upon release of pressure on the

			canister, where in the start configuration, prior to depression of the canister, the count pawl is engaged with a tooth of the ratchet wheel and the actuator pawl is spaced from the ratchet wheel.”
7	<p>“canister fire configuration”</p> <p>’156 Patent, claims 1, 2</p>	<p>Plain and ordinary meaning in view of the claims, specification, and prosecution history.</p> <p>“a configuration of the dose counter in which the medicament canister fires medicament”</p>	<p>“configuration in which the actuator pawl is lower than in the first reset position and below the datum plane and the medicament is ejected”</p>
8	<p>“count configuration”</p> <p>’156 Patent, claims 1, 2</p>	<p>Plain and ordinary meaning in view of the claims, specification, and prosecution history.</p> <p>“a configuration of the dose counter whereby the dosage indicator has indicated a count”</p>	<p>“configuration in which the actuator pawl is further below the datum plane than when in the canister fire position and the dose counter has counted one dose”</p>
9	<p>“datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister”</p> <p>’156 Patent, claim 1</p>	<p>Plain and ordinary meaning in view of the claims, specification, and prosecution history.</p> <p>“a plane that passes through a shoulder of the portion of the inhaler body that engages the valve stem and is perpendicular to the direction of movement of the medicament canister”</p>	<p>“plane or line passing through the bottom surface of a structure into which the valve stem of a medicament canister is inserted, wherein the bottom surface is where the valve stem block meets a passageway to a nozzle for directing the canister contents towards an air outlet”</p>
10	<p>“the body”</p> <p>’156 Patent, claim 12</p>	<p>Plain and ordinary meaning in view of the claims, specification, and prosecution history.</p> <p>“inhaler body” - ’156 Patent, 22:64, 67</p>	<p>This term is indefinite.</p>

		“dose counter body” - ’156 Patent, 22:66	
11	“counter display arranged to indicate dosage information” ’808 Patent, claim 1	Plain and ordinary meaning in view of the claims, specification, and prosecution history. “a component of the dose counter that displays information regarding the number of doses remaining”	“structure displaying the number of doses remaining”
12	“first station” ’808 Patent, claim 1	Plain and ordinary meaning in view of the claims, specification, and prosecution history. “a first region”	“first structure on which the counter is located”
13	“second station” ’808 Patent, claim 1	Plain and ordinary meaning in view of the claims, specification, and prosecution history. “a second region”	“second structure, separate from the first structure, to which the counter display is moved”
14	“different sides” ’512 Patent, claim 1	Plain and ordinary meaning in view of the claims, specification, and prosecution history. “not the same side”	“distinct surfaces where each pin/aperture of the chassis connects to a different face of the body”
15	“formed in the body” ’512 Patent, claim 2	Plain and ordinary meaning in view of the claims, specification, and prosecution history. “located in the body”	“an integrated part of the body”
16	“aperture” ’289 Patent, claim 3 ’587 Patent, claims 3, 13, 20-22	Plain and ordinary meaning in view of the claims, specification, and prosecution history.	“hole”

		“an opening or open space: hole”	
17	“dose counter chamber” '512 Patent, claim 2, 3	Plain and ordinary meaning in view of the claims, specification, and prosecution history. “a chamber of the inhaler in which the dose counter is located”	“space or cavity defined by the main surface of the inner walls and the inner wall through which a portion of the actuation member extends in which the dose counter is located”
18	“separate counter chamber” '156 Patent, claim 12	Plain and ordinary meaning in view of the claims, specification, and prosecution history. “a separate chamber of the inhaler in which the dose counter is located”	“discrete space or cavity defined by the main surface of the inner walls and the inner wall through which a portion of the actuation member extends in which the dose counter is located”
19	“count pawl” '156 Patent, claims 1, 9	Plain and ordinary meaning in view of the claims, specification, and prosecution history. “a pawl that is a component of the dose counter that is capable of engaging with a second tooth of the ratchet wheel”	“a pawl that is part of the dose counter, separate from an actuator pawl, that is arranged to engage with a second tooth different from the first tooth of the ratchet wheel”

C. Claim Terms Whose Construction Will Be Most Significant

Pursuant to L. Pat. R. 4.3(c), Teva contends that none of the terms are more “significant to the resolution of the case,” and that none of the terms’ “construction will be case or claim dispositive or substantially conducive to promoting settlement.” Moreover, Teva anticipates that further discovery may make it unnecessary to construe at least some of the claim terms presently proposed for construction and that it would therefore be an inefficient use of the Court’s and the Parties’ resources to construe all of the terms at this time. Consequently, Teva proposes that the Court construe five claim terms. To the extent that construing additional claim terms proves

necessary, Teva proposes that the parties brief the relevant issues in connection with their filings at that stage of the litigation. Teva welcomes the Court's guidance on this issue.

Defendants contend that the following terms are more "significant to the resolution of the case" as they each relate to elements of the independent claims, or may be dispositive with respect to invalidity or indefiniteness:

- "actuation member"
- "[lying or lie] in a common plane coincident with the longitudinal axis X"
- "canister fire sequence"
- "first reset position"
- "canister fire configuration"
- "count configuration"
- "datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister"
- "first station"
- "second station," and
- "the body"

Defendants disagree with Plaintiffs' attempt to arbitrarily limit the number of terms to be construed. The parties are disputing the construction of 19 terms (14 term groups); 19 terms (14 term groups) should be construed. *See O2 Micro International, Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1361-62 (Fed. Cir. 2008) ("when the parties present a fundamental dispute regarding the scope for a claim term, it is the court's duty to resolve it"). Defendants have repeatedly requested that Plaintiffs' narrow the scope of the claim construction by reducing the number of asserted claims (42), particularly in view of Plaintiffs' stated anticipation that it will

do so, “making it unnecessary to construe at least some of the claim terms” presented. However, as only Plaintiffs are privy to which terms these are, it would be fundamentally unfair to force Defendants to arbitrarily narrow claim construction to just five terms, as Plaintiffs propose. Moreover, dividing claim construction into potentially two steps will needlessly delay resolution of the case. Anticipated Length of Claim Construction Hearing

Pursuant to Local Patent Rule 4.3(d), the parties anticipate that a single-day hearing of seven hours, split evenly between the sides, will be sufficient.

D. Identification of Witnesses for the Claim Construction Hearing

Pursuant to L. Pat. R. 4.3(e), Teva does not presently intend to call any witnesses at the claim construction hearing. Teva reserves the right to call an expert witness to the extent that Defendants’ submissions contain arguments or evidence not disclosed in Defendants’ exchanges or discussed in the parties’ correspondence or meet-and-confer calls. Should that occur, Teva will promptly identify the expert and provide a description of the expert’s proposed testimony.

As set forth in Exhibit A, however, Defendants may rely on expert testimony that would be submitted to the Court by declaration. Despite requests to properly identify any expert whose opinion they intend to rely on in claim construction, Plaintiffs have failed to properly identify any particular expert. Given Plaintiffs’ continued failure to properly disclose expert testimony, Defendants understand that Plaintiffs will not seek to rely on the testimony of an expert whose identity remains undisclosed. Moreover, Plaintiffs’ attempt to reserve the right to disclose an expert for the first time in a rebuttal declaration, leaving Defendants with no chance to chance to cross examine the expert or even submit a response, is not proper and Defendants reserve all rights to move to strike any such declarations.

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